



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Atlanta District Office 5144

60 8th Street, N.E.  
Atlanta, Georgia 30309

January 16, 2001

VIA FEDERAL EXPRESS

P. Wayne Morris  
President  
Age Less Products Inc.  
24101 NC Hwy. 138  
Albemarle, North Carolina 28001

WARNING LETTER  
(01-ATL-23)

Dear Mr. Morris:

This letter is in reference to the marketing and distribution of "Curetage The Only All Natural System for Thinning Hair" by your firm. During an inspection of your facility located at the above address on October 24, 2000, our investigators determined that you are an own-label distributor and [REDACTED] is the contract manufacturer of these products.

The Curetage System includes the Root Stimulator V, Revitalizer IVC, Revitalizer IV, Conditioner III, Cleanser I, Cleanser IC, and Purifier II. All of the product labels include the statement "It's "THE CURE" Not Just The Prevention" and "Promotes the Growth of Thick Healthy Hair". The Root Stimulator V label states "Clinical Studies have shown that the use of the CURETAGE System stops hair loss. Test subjects realized the growth of new, mature hair".

The Revitalizer IVC and IV labels state that the products "will normalize and protect against free radical/oxidants that can contribute to thinning, falling, unhealthy hair...contains proven natural ingredient to stimulate the scalp increasing blood flow and nutrients to the hair roots. Clinical studies have shown that regular use of the CURETAGE System STOPS excessive hair loss". The Cleanser I and IC labels state that "Regular use of this superb cleanser in conjunction with "The System" will stop excessive hair loss and promote the growth of thick healthy hair".

Based on the intended uses described above, the components of the "Curetage System" are drugs (as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)) and is subject to the final rule covering Hair Grower and Hair Loss Prevention Drug Products for Over-the-Counter Human Use in Title 21, Code of Federal Regulations (21 CFR), Part 310.527. Under that rule, no ingredients are generally recognized as safe and effective to grow hair or prevent hair loss. Therefore, the "Curetage System" is a "new drug" (Section 201(p) of the Act). A "new drug" may not be marketed in the United States without an approved new drug application (NDA)(Section 505(a) of the Act). In addition, these products are also misbranded (Section 502(f)(1) of the Act) because they do not bear adequate directions for use for the indications noted above.

These products are also misbranded (Section 502(o) of the Act) because they were manufactured in an establishment not duly registered with FDA as a drug manufacturer and they have not been drug listed as required (Section 510(j) of the Act). These products are further misbranded (Section 502(a) of the Act) because the labels fail to identify Age Less Products as the distributor, rather than the manufacturer of the product (21 CFR 201.1(h)).

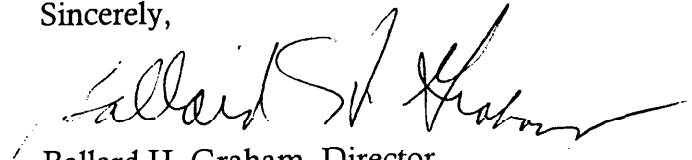
The violations cited in this letter are not intended to be a statement of all the violations that may exist for products marketed by your firm. It is your responsibility to assure that all your products are in compliance with federal laws and regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering contract awards. Failure to promptly correct these violations may result in regulatory action without further notice. Such actions include seizure and/or injunction.

Your product labels also reference your firm's website: [www.curetage.com](http://www.curetage.com). Information from this site was downloaded by you during the inspection and provided to Investigator Garcia. Claims made on the site include "The Only All Natural System for Thinning Hair", "It's "The CURE" Not Just the Prevention", "...the most effective vitamins and organic herbs to combat the thinning and loss of hair", "Our year long study showed that daily use of our Complete System will stop excessive hair loss within 2-3 weeks", and "A twelve month trial was performed by Age Less Products, Inc. prior to recommending Curetage for the treatment of hair loss". Testimonials on the website state "...my hair grew back while I was still taking my chemo treatments", "my hair stopped coming out...and my hair is growing back", and "... I could see new hair growth on top of my head where there was none before". The Root Stimulator V promotion states "A non-drug approach to controlling baldness is to stimulate hair follicles and the blood vessels in the scalp by external means...". These Internet claims may also cause your products to be misbranded.

Within fifteen (15) working days of your receipt of this letter, please notify this office in writing of the specific steps you will take to correct the noted violations. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed. Copies of revised labels, website, and promotional materials should be included with your response.

Your reply should be sent to the Food and Drug Administration at the above letterhead address to the attention of Philip S. Campbell, Compliance Officer.

Sincerely,

A handwritten signature in dark ink, appearing to read "Ballard H. Graham", with a long horizontal flourish extending to the right.

Ballard H. Graham, Director  
Atlanta District

cc:

A series of four horizontal black bars of varying lengths, used to redact the names of the carbon copies (cc) of the letter.